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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,486	10/04/2000	Geoffrey Thomas Andrews	1652-11	8045
23117	7590	08/25/2004	EXAMINER	
NIXON & VANDERHYE, PC			THOMPSON, MICHAEL M	
1100 N GLEBE ROAD				
8TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22201-4714			3763	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/678,486	ANDREWS ET AL.
	Examiner Michael M. Thompson	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05/17/2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or a submitted PTO-1449, they have not been considered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 16-18, 20, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruiz (5,868,779). Ruiz teaches a hollow radially expandable balloon member having terminal portions with a diameter smaller than an intermediate portion, a fluid impervious polyurethane wall wherein the wall has reinforcing fibers integrally with the wall material, a catheter having a tube portion whereby the balloon member can be inflated and deflated by the catheter or tube portion limit radial expansion of the balloon device. Ruiz further teaches Dacron or Kevlar as a possible fiber filament material among others.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 19, 21, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz in view of Andersen et al (4,706,670). Ruiz teaches all of the limitations of the claims except for the reinforcing fibers being made of a braid of filaments of metal or polymeric material in the form of two opposed helices wherein the braid has a critical angle and the opposed helices are oriented to one another at or adjacent to the critical angle. Andersen et al. teaches reinforcing fibers being made of a braid of filaments of metal or polymeric material in the form of two opposed helices wherein the braid has a critical angle and the opposed helices are oriented to one another at or adjacent to the critical angle. It would have been obvious to one

of ordinary skill in the art, at the time of invention to have simply substituted or modified the reinforcing fibers taught by Ruiz with the reinforcing fibers and materials taught by Andersen et al. for the well known purpose of enhancing the strength and stiffness of the inflated balloon as taught by Andersen et al. Furthermore, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have provided that the maximum limit of radial expansion to not more than 115% of the maximum unstretched radially expanded state because Applicant has not disclosed that limiting radial expansion to not more than 115% provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with limiting radial expansion to not more than any reasonable percent or not more than specifically 115%. Therefore, it would have been an obvious matter of design choice to modify Cook to obtain the invention as specified by Applicant for the well known purpose of preventing over-expansion of a balloon device within the vasculature of a patient to prevent rupture or tearing of the vessel.

***Response to Arguments***

7. Applicant's arguments filed 05/17/2004 have been fully considered but they are not persuasive. On the outset, the Examiner would like to thank Applicant for acknowledging the accidental reference to Cook in the rejection. Accordingly, this minor discrepancy has been changed to reflect the rejection of record. The Examiner contends that the Ruiz reference anticipates Applicant's claims. It is the Examiner's position that the limitations of the claims are properly met as recited, "the wall of the balloon member...having reinforcing fibres provided integrally *with* the wall material," by broad interpretation of the claim language in conjunction

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with the definition of “integral or integrally. A broad interpretation of the claimed limitations merely recite a wall member having reinforcing fibres provided *with* the wall material in a integral fashion leading one to interpret an acceptable definition of the word “integrally.” As per Merriam-Webster's Online Dictionary, 10th Edition, integrally is defined as, “formed as a unit with another part” or “composed of integral parts” and finally “**a** : essential to completeness : CONSTITUENT <an *integral* part of the curriculum>.” When one further considers the term constituent one finds a definition stating, “**3** : an essential part : COMPONENT, ELEMENT” Therefore, it is the Examiner's position that the limitations of the claims only recited that the reinforcing fibres are provided integrally with the wall material. It is submitted that Ruiz has a wall material that is flexible and a fluid impervious material that is integral with reinforcing fibres. In conclusion, it is understood that Applicant has fully responded to all rejections and raised all errors with respect to the Examiner's rejection and since there is no further traversal beyond the above-mentioned issues it appears that Applicant has acquiesced to all other rejections of record and the instant Office Action has been made Final.

### *Conclusion*

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

  
BRIAN L. CASLER  
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MT 

August 15, 2004